



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1147]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0541. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to  
the Center for Food Safety and Applied Nutrition

OMB Control Number 0910-0541--Extension

As an integral part of our decision making process, we are obligated under the National Environmental Policy Act of 1969 (NEPA) to consider the environmental impact of our actions, including allowing notifications for food contact substances to become effective; approving food additive petitions, color additive petitions, generally recognized as safe affirmation petitions, and requests for exemption from regulation as a food additive; and approving actions on certain food labeling citizen petitions, nutrient content claims petitions, and health claims petitions. We have provided guidance that contains sample formats to help industry submit a claim of categorical exclusion (CE) or an environmental assessment (EA) to the Center for Food Safety and Applied Nutrition (CFSAN). The document entitled “Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition” identifies, interprets, and clarifies existing requirements imposed by statute and regulation, consistent with the Council on Environmental Quality regulations (40 CFR 1507.3). It consists of recommendations that do not themselves create requirements; rather, they are explanatory guidance for our own procedures in order to ensure full compliance with the purposes and provisions of NEPA.

The guidance provides information to assist in the preparation of claims of CE and EAs for submission to CFSAN. The following questions are covered in this guidance: (1) What types of industry-initiated actions are subject to a claim of categorical exclusion? (2) What must

a claim of categorical exclusion include by regulation? (3) What is an EA? (4) When is an EA required by regulation and what format should be used? (5) What are extraordinary circumstances? and (6) What suggestions does CFSAN have for preparing an EA? Although CFSAN encourages industry to use the EA formats described in the guidance because standardized documentation submitted by industry increases the efficiency of the review process, alternative approaches may be used if these approaches satisfy the requirements of the applicable statutes and regulations.

*Description of Respondents:* The likely respondents include businesses engaged in the manufacture or sale of food, food ingredients, and substances used in materials that come into contact with food.

In the *Federal Register* of June 25, 2019 (84 FR 29864), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

| 21 CFR Section/Environmental Impact Considerations | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response | Total Hours |
|--|--------------------|---------------------------------|------------------------|-----------------------------|-------------|
| 25.15(a) and (d) (to cover CEs under 25.32(i))     | 47                 | 1                               | 47                     | 8                           | 376         |
| 25.15(a) and (d) (to cover CEs under 25.32(o))     | 1                  | 1                               | 1                      | 8                           | 8           |
| 25.15(a) and (d) (to cover CEs under 25.32 (q))    | 3                  | 1                               | 3                      | 8                           | 24          |
| 25.40(a) and (c) EAs                               | 57                 | 1                               | 57                     | 180                         | 10,260      |
| Total  |                    |                                 |                        |                             | 10,668      |

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimates for respondents and numbers of responses are based on the annualized numbers of petitions and notifications qualifying for CEs listed under § 25.32(i) and (q) (21 CFR 25.32(i) and (q)) that we have received in the past 3 years. To avoid counting the burden

attributed to § 25.32(o) as zero, we have estimated the burden for this categorical exclusion at one respondent making one submission a year for a total of one annual submission. The burden for submitting a categorical exclusion is captured under 21 CFR 25.15(a) and (d).

To calculate the estimate for the hours per response values, we assumed that the information requested in this guidance for each of these three categorical exclusions is readily available to the submitter. For the information requested for the exclusion in § 25.32(i), we expect that the submitter will need to gather information from appropriate persons in the submitter's company and to prepare this information for attachment to the claim for categorical exclusion. We believe that this effort should take no longer than 8 hours per submission. For the information requested for the categorical exclusions in § 25.32(o) and (q), the submitters will copy existing documentation and attach it to the claim for categorical exclusion. We believe that collecting this information should take no longer than 8 hours per submission.

For the information requested for the environmental assessments in 21 CFR 25.40(a) and (c), we believe that submitters will submit an average of 57 environmental assessments annually. We estimate that each submitter will prepare an EA within 3 weeks (120 hours) and revise the EA based on Agency comments (between 40 to 60 hours), for a total preparation time of 180 hours.

Based on a current review of the information collection, we have made no adjustments to the currently approved estimate.

Dated: November 14, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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